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EXAMINER

RAHMANI, NILOOFAR

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08/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/516,500
Filing Date: December 02, 2004
Appellant(s): HANCKE OROZCO ET AL.

MAILED
AUG 29 2007
GROUP 1600

Mark Pohl
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/13/2007 appealing from the Office action mailed 01/19/2007.

(1) Real Party in Interest

The real party in interest is HP Ingredients, Inc., a Florida corporation.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of invention is correct with exception of:

- (1) The structure shown on page 2, line 15 for the compound is unclear as the substituents carbon #3 and carbon 4, carbon #3 should be CH₂OH and carbon #4 should be H.
- (2) Claim 53 is drawn to a method comprising diagnosing in a patient a disease, then administering a drug to a patient.

Claim 66 is drawn to a method comprising diagnosing in a patient a disease, then administering a drug to a patient.

Claim 73 is drawn to a method comprising identifying in a person the possible presence of Syndrome X and then administering a drug to a patient.

(6) Grounds of Rejection to be Reviewed on Appeal

(1) 102(b) rejection of claims 53-73 over **Panossian** et al. Phytomedicine, Vol. 9, pages 598-605, **Wheelock** et al. US 5,833,994, **Babish** et al. WO 96/17605, **Nanduri** et al. US 6,410,590, **Babish** et al. US 2002/0077350. As evidenced by **Samaha** et al., Journal of the American heart association, 2006, Vol. 26, pages 624-630, **Vasantha** et al., Journal of biomolecular screening, 2006, Vol. 11, pages 959-967, and web page from NIH definition Syndrome X (<http://familydoctor.org/online/famdocen/home/common/heartdisease/basics/826.p rinterview>).

(7) Grouping of claims

The rejections of claims 53-73 stand or fall together because appelleant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192 (C)(7).

(8) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior art of record

Panossian et al. Phytomedicine, Vol. 9, pages 598-605.

Wheelock et al. US 5,833,994.

Babish et al. WO 96/17605.

Nanduri et al. US 6,410,590.

Babish et al. US 2002/0077350.

(10) New Articles

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Samaha et al., Journal of the American heart association, 2006, Vol. 26, pages 624-630.

Vasantha et al., Journal of biomolecular screening, 2006, Vol. 11, pages 959-967.

<http://familydoctor.org/online/famdocen/home/common/heartdisease/basics/826.p rinterview>.

(11) Grounds of Rejection

Claims 53-73 are rejected under 102(b). This rejection is set forth in a prior Office Action, mailed on 01/19/2007 and 03/16/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

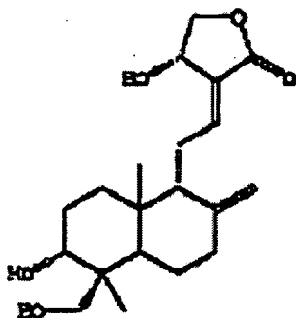
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) Claims 66-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Panossian et al., Phytomedicine, Vol. 9, pages 598-605. on page 608, the compound Andrographolide is encompassed by the instant compound claimed with the same activity i.e. induce tumor necrosis factor-alpha (TNF- α) and Interleukin-2, see summary. Therefore, the instant claims are anticipated with the same utility by Panassian et al.

(b) Claims 53, 65-66, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Wheelock et al., US 5,833,994. On column 21, lines 49-52, the compound Andrographolide which is extracted from the Andrographis Paniculata plant which has activity as treating AID's, anticancer, HIV, viral infection.

(c) Claims 53, and 64-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al., WO 96/17605. On page 16, lines 15-16, the compound Andrographolide is encompassed by the instant compound claimed with the same activity i.e. Alzheimer, AIDS, see page 9, lines 12-24. Therefore, the instant claims are anticipated with the same utility by Babish et al.

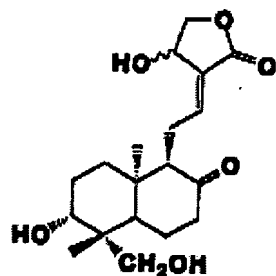
(d) Claims 53-63,66, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanduri et al., US 6,410,590. On column 8, lines 10-25, the compound of formula (II)



anticipates the instant compound claimed which is obtained from the same family of plant *Andrographis Paniculata* (column 2) having the activity such as autoimmune diseases, AIDS, HIV, and cancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

(e) Claims 53-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Babish et al., US 2002/0077350. On sheet 2, the compound [C3], Andrographolide

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is encompassed by the instant compound claimed with the same activity i.e. antihyperlipidemia (one factor of Syndrome X), see page 6, paragraph 49, anti-inflammatory, Alzheimer disease, AIDS, see page 1, paragraph 1-5. Therefore, the instant claims are anticipated with the same utility by Babish et al.

(12) Response to Argument

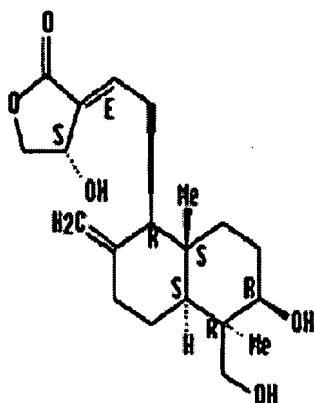
1) **The summary of Appellants** the art cited does not teach the instantly claimed compound, which is

3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone

2) **It is Examiner's position that** the prior art of record does teach the claimed compound, Andrographolide, which IUPAC name is

3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone.

The structure of compound is shown to be



, as Registry (RN) No. 5508-58-7. Thus, the compound of the reference is the same as the claimed compound, Andrographolide, even though different structures are disclosed.

The locations of the teachings of the references are reiterated below:

Claim 53 is taught by **Wheelock et al.**, US 5,833,994, **Nanduri et al.**, US 6,410,590, and **Babish et al.**, WO 96/17605.

Wheelock et al. disclosed **Andrographolide** on column 6, line 23 and **AIDS** on column 6, lines 33-37.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract.

Babish et al. WO 96/17605 disclosed **Andrographolide** on page 6, line 8 and **AIDS**, **Alzheimer's** on page 7, lines 6-9 and page 34, line 21.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 and **Alzheimer's** on Example 11, **Antiflammary** on abstract, **Psoriasis** on Example 10, **Osteoarthritis** on Exampe 14 .

Claim 54 is taught by **Nanduri et al.**, US 6,410,590 .

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Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract.

Claim 55 is taught by **Nanduri et al.**, US 6,410,590 and **Babish et al.**, US 2002/0077350.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **rheumatoid arthritis** is autoimmune disease.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2, **Osteoarthritis** on Exampe 14 .

Claim 56 is taught by **Nanduri et al.**, US 6,410,590.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **lupus exanthematous** is autoimmune disease.

Claim 57 is taught by **Nanduri et al.**, US 6,410,590 and **Babish et al.**, US 2002/0077350.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **multiple sclerosis** is autoimmune disease.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 and **Osteoarthritis** on Exampe 14 .

Claim 58 is taught by **Nanduri et al.**, US 6,410,590.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **asthma** is autoimmune disease.

Claim 59 is taught by **Nanduri et al.**, US 6,410,590.

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Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **allergic reaction** is autoimmune disease.

Claim 60 is taught by **Nanduri et al.**, US 6,410,590 and **Babish et al.**, US 2002/0077350.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **psoriasis** on abstract.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 **Psoriasis** on Example 10.

Claim 61 is taught by **Nanduri et al.**, US 6,410,590 and **Babish et al.**, US 2002/0077350.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract, wherein **osteoarthritis** is autoimmune disease.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2, **Osteoarthritis** on Example 14 .

Claim 62 is taught by **Nanduri et al.**, US 6,410,590.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **diabetes** on column 82, line 64.

Claim 63 is taught by **Nanduri et al.**, US 6,410,590.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract.

Claim 64 is taught by **Babish et al.**, WO 96/17605 and **Babish et al.**, US 2002/0077350.

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Babish et al. disclosed **Andrographolide** on page 6, line 8 and page 16, lines 15-16 and **Alzheimer's disease** on page 34, line 21.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 and **Alzheimer's** on Example 11.

Claim 65 is taught by **Babish et al.**, WO 96/17605 and **Wheelock et al.**, US 5,833,994.

Babish et al. disclosed **Andrographolide** on page 6, line 8 and page 16, lines 15-16 and **AIDs** on page 7, lines 6-9 and **Wheelock et al.** disclosed **Andrographolide** on column 6, line 23 and **AIDs** on 6, lines 33-37.

Claim 66 is taught by, **Nanduri et al.**, US 6,410,590.

Nanduri et al. disclosed **Andrographolide** on column 2, line 26 and **Autoimmune disease** on abstract.

Claim 67 is taught by, **Babish et al.**, WO 96/17605 and **Panossian et al.**, and **Samaha et al.**, and **Vasantha et al.**

Babish et al. disclosed **T-cell** on page 15, line 11 and page 32, lines 26-28, therefore, inherently disclosed peroxysome proliferators activated receptor γ (PPAR- γ).

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)**.

Samaha et al. disclosed the link between PPAR- γ and interleukin (IL).

Vasantha et al. disclosed the link between **Receptor γ** and **NF-KB** and **INF- α** and **interleukin-2 (IL-2)** and **PPAR- γ** .

Claim 68 is taught by, **Babish et al.**, WO 96/17605 and **Panossian et al.**

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Babish et al. disclosed **T-cell** on page 15, line 11 and page 32, lines 26-28, therefore, inherently disclosed inflammatory cytokine.

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)**.

Claim 69 is taught by, **Babish et al.**, WO 96/17605 and **Panossian et al.**

Babish et al. disclosed **T-cell** on page 15, line 11 and page 32, lines 26-28, therefore, inherently disclosed inflammatory cytokine.

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)**.

Claim 70 is taught by **Panossian et al.**

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)**.

Claim 71 is taught by **Panossian et al.** in view of **Vasantha et al.**

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)** and **TNF- α** .

Vasantha et al. disclosed **NF-KB** and **PPAR- γ** and **TNF- α** .

Claim 72 is taught by **Babish et al.**, US 2002/0077350 and **Wheelock et al.** in view of **Babish et al.** WO 96/17605.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 and **T-Cell** on Examples 1-7.

Wheelock et al. disclosed **Andrographolide** on column 6, line 23 and **T-cell** on column 8, line 55.

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Babish et al. disclosed **Andrographolide** on page 6, line 8 and page 16, lines 15-16 and **T-cell** on page 15, line 11 and page 32, lines 26-28.

Claim 73 is taught by **Babish** et al., US 2002/0077350 and **Samaha** et al. in view of **Nanduri** et al. and **Panossian** et al. and webpage from NIH.

Babish et al., US2002/0077350 disclosed **Andrographolide** on sheet 2, compound[C3], page 5, column 2 and **Bowel Syndrome** on Example 13.

Samaha et al. disclosed the link between **PPAR- γ** and **Metabolic Syndrome** on summary.

Nanduri et al. disclosed **Andrographolide** on page 6, line 8 and page 16, lines 15-16 and **diabetes** on column 82, line 64.

Panossian et al. disclosed **Andrographolide** on summary and **INF- γ** and **interleulin-2 (IL-2)** and **TNF- α** .

NIH website teaches one symptom of **Syndrome X** is **diabetes**.

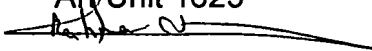
Thus the references above teach the Andrographolide (i.e.

3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone compound with all the claimed limitations to treat the same diseases as the instant claims. Therefore, the rejections are proper.

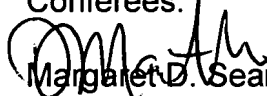
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